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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/038,288 | 11/09/2001 | D. Wade Walk | LEX-0268-USA | 6712 |

7590 04/29/2003

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|-----------------|--------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 10/038,288 | WALKE ET AL. |
| Examin r | Art Unit | |
| David J. Steadman | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) ____ is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) 1-7 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. ____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

6) Other: _____

DETAILED ACTION

Application Status

[1] Claims 1-7 are pending in the application.

Election/Restrictions

[2] Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1-3, drawn to an isolated nucleic acid encoding SEQ ID NO:2 including SEQ ID NO:1 and a recombinant expression vector comprising a sequence encoding SEQ ID NO:2, classified in class 435, subclass 320.1.
- II. Claim(s) 3, drawn to a recombinant expression vector comprising a sequence encoding SEQ ID NO:4, classified in class 435, subclass 320.1.
- III. Claim(s) 4, drawn to a substantially isolated protein having the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 350.
- IV. Claim(s) 4, drawn to a substantially isolated protein having the amino acid sequence of SEQ ID NO:4, classified in class 530, subclass 350.
- V. Claim(s) 5 and 7, drawn to an isolated polynucleotide comprising at least 24 contiguous nucleotides of SEQ ID NO:6 and a recombinant expression vector comprising a sequence encoding SEQ ID NO:7, classified in class 435, subclass 320.1.
- VI. Claim(s) 6, drawn to a substantially isolated protein of SEQ ID NO:7, classified in class 530, subclass 350.

[3] The inventions are distinct, each from the other because:

[4] The nucleic acids of Groups I, II, and V are structurally distinct molecules that encode different polypeptides and no single nucleic acid of Groups I, II, or V would render any of the others obvious to one of ordinary skill in the art.

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[5] The proteins of Groups III, IV, and VI are structurally distinct molecules that elicit different antibodies and no single protein of Groups III, IV, or VI would render any of the others obvious to one of ordinary skill in the art.

[6] The nucleic acids of Groups I, II, and V and the proteins of Groups III, IV, and VI each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The nucleic acid of Groups I, II, and V have other utility besides encoding polypeptides such as being used as hybridization probes and the proteins of Groups III, IV, and VI can be made by another method such as purification from the natural source or chemical synthesis.

[7] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-VI are distinct for the reasons given above and each of the inventions requires a separate patent and non-patent literature and sequence search, restriction for examination purposes is proper.

[8] A telephone call was made to Mr. David Hibler on 04/23/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

[9] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[10] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[11] It is noted that claims 3 and 4 will be examined to the extent the claims read on the elected subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

Patent Examiner

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04/28/03

